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THE IMPACT OF DOSIMETRY UNCERTAINTIES ON DOSE-RESPONSE ANALYSES

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Abstract

Radiation dose estimates used in epidemiological studies are subject to many sources of uncertainty, and the error structure may be a complicated mixture of different types of error. Increasingly, efforts are being made to evaluate dosimetry uncertainties and to take account of them in statistical analyses. The impact of these uncertainties on dose response analyses depends on the magnitude and type of error. Errors that are independent from subject to subject (random errors) reduce statistical power for detecting a dose-response relationship, increase uncertainties in estimated risk coefficients, and may lead to underestimation of risk coefficients. The specific effects of random errors depend on whether the errors are “classical” or “Berkson.” Classical error can be thought of as error that arises from an imprecise measuring device, whereas Berkson error occurs when a single dose is used to represent a group of subjects (with varying true doses). Uncertainties in quantities that are common to some or all subjects are “shared” uncertainties. Such uncertainties increase the possibility of bias, and accounting for this possibility increases the length of confidence intervals. In studies that provide a direct evaluation of risk at low doses and dose rates, dosimetry errors are more likely to mask a true effect than to create a spurious one. In addition, classical errors and shared dosimetry uncertainties increase the potential for bias in estimated risks coefficients, but this potential may already be large due to the extreme vulnerability to confounding in studies involving very small relative risk.

Keywords

analysis; statistical; dosimetry; epidemiology; National Council on Radiation Protection and Measurements

INTRODUCTION

Radiation epidemiology is characterized by the fact that radiation can be more reliably measured than most other exposures. Extensive efforts have been made not only to quantify exposure, but to estimate a biologically relevant quantity called dose. This has made it possible to evaluate the shape of the dose-response function, to estimate the risk per unit of dose (for linear dose-response functions), and to investigate the dependency of the dose-

response on factors such as dose rate, age, and sex. Relevant to the overall topic of this proceedings, data on persons exposed at low doses (and/or low dose rates) can be used to test for dose-response relationships and to estimate risk coefficients. These risk coefficients are often compared with those obtained from studies of persons exposed at high doses (and/or high dose rates).

Dose estimates used in epidemiologic studies are subject to many sources of uncertainty. Because dose assessment is often complex and conducted many years after the exposures occurred, these uncertainties may be large. There is obviously interest in understanding how dosimetry uncertainties might impact results of dose-response analyses and how they should be accounted for to obtain appropriate inferences.

This paper provides a non-technical discussion of dosimetry uncertainties, and does not claim to provide a statistically rigorous treatment. It focuses on distinguishing different types of errors and their potential impact on epidemiologic dose-response analyses, and gives only limited attention to statistical approaches for taking account of dosimetry uncertainties. The paper draws on Schafer and Gilbert (2006), and readers are referred to this paper (and the references it provides) for a more statistically rigorous treatment. Other general references are Armstrong (1990), Thomas et al. (1993), and Strom (2008).

TYPES OF ERROR

A common model for measurement error is as follows:

$$\textit{estimated dose} = \textit{true dose} + \textit{error}, \quad (1)$$

where the “error,” which is unknown, is defined as the difference in the estimated and true doses. Often, however, it is more convenient to express “error” as a percentage of the true dose. That is, estimated dose = true dose × error factor. On a log scale, this becomes

$$\log(\textit{estimated dose}) = \log(\textit{true dose}) + \log(\textit{error factor}). \quad (2)$$

Most research on the effects of dose uncertainties on epidemiologic dose-response analyses is based on the assumption that errors do not depend on whether a subject has the health effect being studied; such errors are said to be non-differential. Such a dependency might come about if greater efforts were made to estimate doses of persons who developed disease than of persons who did not develop disease. It is assumed in this paper that errors are non-differential.

The impact of uncertainties on dose-response analyses depends on whether errors follow a classical or Berkson model. With the classical model, the error is independent of the true dose. Classical error can be thought of as measurement error or error that arises from an imprecise measuring device such as a film dosimeter. If several dosimeters are exposed to exactly the same dose, there is variability in the response. With classical error, the estimated doses vary about the true dose, and the variance of the estimated doses is larger than the variance of the true doses. In conducting dose-response analyses, the presence of classical error spreads out the response horizontally and attenuates it toward the null. With a true

positive linear dose-response, the estimated slope will be lower than the true one. Classical error can also distort the shape of the dose-response.

The Berkson error model applies when the error is independent of the estimated dose (in contrast to classical error, which is independent of the true dose). It can be thought of as a grouping error that results when a single estimated dose such as a group mean is used to represent a group of subjects with variable doses. Schafer and Gilbert (2006) use the term “individual peculiarity” for Berkson error since it is the difference in the dose of an individual from the group dose that has been assigned. With Berkson error, the variance of the true doses is larger than the variance of the estimated doses. Since each estimated dose actually comes about from a range of true doses, there is more variability in the response. However, provided that the assigned doses are the means of the true doses in the groups, there is no distortion of a linear dose-response. Cox et al. (1999) and Strom (2008) provide useful graphical illustrations of the effects of both classical and Berkson error on linear dose-response analyses.

An example of Berkson error is the assignment of a single exposure to a group of underground miners in a particular location and time period. Another example is the use of a single factor to convert “recorded” external doses to organ doses in nuclear worker studies when the true factor depends on the specific radiation environment of the worker to whom it is assigned. Still another example is the use of a prediction model (function) with several parameters to convert available measurements to doses. For example, models that quantify the behavior of plutonium in the body are used to obtain estimates of dose to various organs from urine measurements. In such cases, Berkson error comes about because such models are not likely to apply exactly to all individuals.

In many situations involving Berkson error, there may also be errors in the group means that are assigned to individuals, or, in the case of a prediction model, errors in parameters of the model or in the functional form of the model. These errors are usually classical, not Berkson. The term “Berkson error” refers only to the error that arises from grouping, that is, the departure of the individual dose from the group mean (or from the dose obtained from a prediction model).

Thus far, the discussion has been of errors that are independent from subject to subject. Errors can also be correlated or “shared” for different subjects. For example, an error in the yield of the Hiroshima bomb would affect all Hiroshima survivors in a similar manner, and thus this error would be “shared” by these survivors.

A simple example of shared error is one in which the expected value of the estimated dose is a constant K times the true dose. If estimates of linear risk coefficients were based on such doses, they would be biased by a factor K . If the value of K were known, one would simply correct the dose estimates. More realistically, a parameter used in dose estimation (such as the yield of the Hiroshima bomb) is not known with certainty, and a best estimate of the parameter is used. Ideally, confidence intervals for risk coefficients should reflect the uncertainty in the estimated parameter.

Usually the situation is more complicated than that noted above. The expected value of the estimated dose may depend in a complicated way on the true dose and several uncertainly estimated parameters. This would be the case, for example, in estimating thyroid dose in studies of persons exposed environmentally to ¹³¹I (Stram and Kopecky 2003) or in estimating internal doses in studies of nuclear workers exposed to plutonium (Khokhryakov et al. 2005; Leggett et al. 2005). In addition, different subgroups of subjects may share different errors. For example, errors in the yield of the Hiroshima bomb are shared by Hiroshima survivors, whereas errors in the yield of the Nagasaki bomb are shared by Nagasaki survivors.

EFFECTS OF ERROR IN DOSES ON DOSE-RESPONSE ANALYSES

There are several possible effects of error in doses on dose-response analyses if no efforts are made to account for such errors. First, estimated linear risk coefficients (estimates of risk per unit of dose) can be biased. With classical random error, positive risk coefficients are usually underestimated. Shared error, such as error in parameters that are used to estimate doses of many subjects, can also lead to bias, which could be in either direction. Confidence limits for the estimated risk coefficients will also be biased.

In addition, both classical and Berkson errors can distort the shape of the dose-response function. Errors in parameters of prediction models for converting measurements to doses might also have this effect. The shape of the dose-response is important in using higher dose data to estimate risks at low doses, and there is often interest in distinguishing linear from linear-quadratic dose-response functions. Most epidemiologic studies have limited power for making such distinctions; the presence of dosimetry uncertainties adds to the difficulties.

Still another effect is that uncertainty in estimated parameters is likely to be underestimated, particularly if the uncertainty in shared parameters is not taken into account. In addition, if other variables that are correlated with radiation dose are being evaluated, adjustments for dose may not be adequate if dose is measured with error.

Finally, both classical and Berkson random errors lead to reduction in statistical power, an effect that may be particularly important in studies of persons exposed at low doses where power may already be very limited. However, tests of statistical significance based on imprecisely measured doses are usually valid. In general, dose uncertainties are much more likely to mask a true dose-response than lead to a spurious one.

ACCOUNTING FOR DOSE UNCERTAINTIES

It should be emphasized that statistical adjustments can never be a substitute for reducing dosimetry uncertainties, and one should try to improve dose estimates if there is a reasonable possibility for doing so. Specifically, statistical adjustments can't improve statistical power or provide more precise estimates of risk, and are unlikely to greatly modify the statistical significance of a dose-response. What they can do is to avoid misleading results and correct for biases in risk coefficients and confidence limits. Accounting for classical error will usually increase risk coefficients and their confidence limits.

Statistical approaches for addressing dosimetry uncertainties are often complex and computer intensive. Applying these approaches requires an understanding of the error structure, which can be challenging to achieve in situations with complicated mixtures of different types of error. It is necessary to identify the sources of error, determine whether each is classical or Berkson, and if various errors are independent from subject to subject or shared. For shared error, one needs to know which errors are shared by whom.

Once sources of error have been identified, their magnitude needs to be described using statistical distribution functions. For example, errors in location of A-bomb survivors have been described by normal distribution functions, which result to lognormal distributions for the errors in doses (Pierce et al. 1990). Since it is rare that hard data on all sources of dose uncertainty are available, subjective judgments are usually required in quantifying uncertainties. One might say that the uncertainties themselves are uncertain. Thus, it may be useful to conduct analyses based on alternative assumptions about the nature and magnitude of errors.

A single standard error for a dose estimate is usually not adequate since it is necessary to distinguish classical and Berkson errors and to specify the correlation structure. To understand and address dose uncertainties in complex dosimetry systems, it is probably essential that statisticians work very closely with dosimetrists. A brief description of some of the approaches that have been used for statistical adjustment of uncertainties is given by Schafer and Gilbert (2006).

Efforts to take account of errors in dose estimates have been made in several radiation epidemiology studies. Adjustments resulted in increasing linear risk estimates by about 10% in Japanese A-bomb survivor studies (Pierce et al. 1990; Preston et al. 2007), by 50–100% in studies of persons exposed to residential radon (Lagarde et al. 1997; Darby et al. 1998; Reeves et al. 1998; Wang et al. 2002), and by 30% and 300%, respectively, in studies of leukemia and thyroid in relation to doses from fallout in Utah (Thomas 1999). For the underground miners, taking account of error decreased the estimate of the magnitude of the inverse exposure-rate effect (Stram et al. 1999). The relative uncertainty was increased in studies where this was addressed (Reeves et al. 1998; Thomas 1999; Wang et al. 2002; Mallick et al. 2002; Stayner et al. 2007). In a study of tinea capitis patients (Schafer et al. 2001; Lubin et al. 2004), adjustments modified results very little. The estimated statistical power was reduced in the Hanford thyroid study (Stram and Kopeccky 2003).

STUDIES OF PERSONS EXPOSED AT LOW DOSES

In this section, special attention is given to the effects of dosimetry error in studies of persons exposed at low doses. Examples include most studies of nuclear workers, studies of persons exposed to residential radon, and the more than 20,000 Japanese atomic bomb survivors with doses less than 0.1 Gy; these survivors are often evaluated separately to gain direct information on low doses. Objectives of these studies, which provide direct assessments of risks at low doses, are to determine if there is direct evidence of risk at low doses, and to evaluate whether risk estimates based on low dose data are compatible with those obtained from higher dose studies.

Studies of nuclear workers exposed primarily to external sources are used as an illustration of dosimetry uncertainties in a low dose setting. External dose estimates for these workers are based on dosimeters worn by the workers, and usually dose estimates are available for each year of employment at the nuclear facility of interest. Here, just two sources of error are considered. For a more comprehensive discussion, the reader is referred to Thierry-Chef et al. (2007) or Gilbert et al. (2006).

The first type of error is laboratory error, or the intrinsic sampling variation in measurements obtained from dosimeters. This error is a classical error. Although laboratory error can be very important in a single dosimeter measurement, it probably does not have much impact on nuclear worker dose-response analyses. This is because the higher cumulative doses that tend to drive dose-response analyses are the sums of large numbers of independent readings so that the relative error in these cumulative doses is small (Gilbert 1998).

A more important source of error is that doses recorded in the records of nuclear workers are not unbiased estimates of dose to the bone marrow and other organs of the body. The objective of radiation monitoring programs was usually to estimate the dose at 10 cm depth in tissue, a measure that is adequate for radiation protection purposes but not ideal for epidemiology. The relationship of recorded and organ doses depends on the dosimeter that was used and on the radiation environment (specifically, the energy of the radiation and the geometry of the exposure).

The largest nuclear worker study is the 15-country worker study (Cardis et al. 2005, 2007) mentioned by Shore (2009). This study, which was coordinated by the International Agency for Research on Cancer, included extensive efforts to address dosimetry uncertainties (Thierry-Chef et al. 2007). A dosimetry subcommittee of both epidemiologists and dosimetrists from several countries was formed and met several times. All participating facilities filled out detailed questionnaires on their dosimetry practices. In addition, special studies of a representative nuclear power plant and of a mixed activities facility were conducted, and representative dosimeters were tested.

As a result of these efforts, factors for converting recorded doses to organ doses were developed and applied to the doses used in the 15-country epidemiologic analyses (Cardis et al. 2005, 2007). In addition, uncertainty in these factors was evaluated and characterized using lognormal distributions. The “correct” factor for an individual worker depends on the dosimeter used and on the energy and geometry of the radiation environment. Because it was not possible to characterize these environments for individual workers, factors were developed for groups of workers defined by time period and type of facility.

There is Berkson error in these factors due to the variation in radiation environments among the workers within the groups for which factors were developed. In addition, there is uncertainty in whether the factors assigned to the groups are the correct means for the groups. This error is a classical error that is shared by workers in the same group. This type of error structure is a common one and applies in many situations where prediction models are used to estimate doses. Reeves et al. (1998) provide a more rigorous discussion of such mixtures of error in the context of error in residential radon exposures.

For perspective, it should be kept in mind that low dose epidemiologic studies are subject to limitations other than dose uncertainties as noted by Shore (2009) and Gilbert (2001). In many low dose studies, the increased risk for more highly exposed subjects is likely to be only a few percent. Such studies have low statistical power and imprecisely estimated risks even when the number of subjects is very large as in the 15-country nuclear worker study. In addition, it is impossible to insure that an epidemiologic study is free from serious bias due to confounding when estimating very small risks.

In nuclear worker studies, doses in the range 0.1 to 0.2 Gy tend to be most influential in dose-response analyses. The predicted relative risks for solid cancers based on BEIR VII (NRC 2006) models are, respectively, 1.02 and 1.03 for doses of 0.1 and 0.2 Gy. Studies of environmental exposures often involve even lower doses with accordingly lower relative risks. In these situations, confounding by variables with much larger relative risks can be problematic. For example, if higher dose subjects are even slightly more likely to smoke than lower dose subjects, this can easily distort very small relative risks. In general, studies involving small relative risks are much more vulnerable to confounding than studies involving large relative risks.

CONCLUSION

The most important effects of dose uncertainties in low dose epidemiologic studies are as follows. First, they increase the potential for bias in estimates of linear risk coefficients with classical error biasing risk estimates downward. However, in low dose studies, confounding probably has a much greater potential for biasing risk estimates than dose uncertainties. Second, dose uncertainties reduce the already limited statistical power for detecting dose-response relationships. In summary, dose uncertainties are much more likely to mask a true dose-response than lead to a spurious one. A lack of dose-response in a low dose study can usually be explained by low statistical power in combination with dosimetry uncertainties, and tells us very little about thresholds and low dose linearity.

Uncertainties in doses used in epidemiologic studies (regardless of the dose level) are increasingly being evaluated and taken into account in dose-response analyses. Such efforts require careful specification of the error structure, and considerable communication between dosimetrists and the statisticians who perform the dose-response analyses.

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